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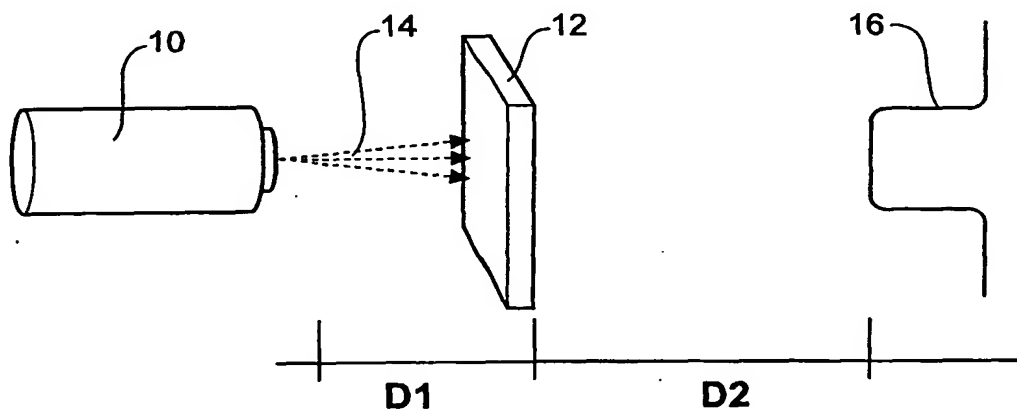
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(54) Title: LASER BEAM HOMOGENISERS IN MEDICAL APPLICATIONS



(57) Abstract: A device is disclosed usable for low level laser therapy to induce a photochemical reaction (non-heating) which is used in the treatment of conditions like tendonitis and other soft tissue injuries, wound healing and pain relief. The arrangement proposed will allow the device to be a Class I laser device thus providing long term minimization of the running costs of the device. The device includes a laser generating means (10) for generating a laser beam (14), the laser generating means (10) having an apparent source size and homogenising means (12) for modifying the laser beam (14) for modifying the apparent source size of the laser beam (14).

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LASER BEAM HOMOGENISERS IN MEDICAL APPLICATIONS

FIELD OF THE INVENTION

This invention relates to laser systems and in particular to lasers used in the medical field.

BACKGROUND OF THE INVENTION

Safety when using or being exposed to lasers is a very important consideration. International Standards exist with regards to the classification of laser devices and the way in which different classes of laser can be used. Those laser devices that conform to the laser safety Class I definition (ie IEC825-1, AS2211) are considered the safest.

Laser emitting devices that do not fall within the Class I definition require the device and the user, and in medical applications the patient, to use or be subject to one or more of the following: use of safety spectacles, interlock systems, warning lights, etc.

Laser emitting devices have a wide range of wavelength, energy and pulse characteristics and the classification system is a guide as to the way in which each device having one or more of those characteristics can be used and by whom the device can be used.

A Class I laser-emitting device can be used without restriction but in accordance with the manufacturer's instructions for the purpose for which it was designed. This means that special training and additional safety equipment is not required. Thus operating costs are less when compared to the attendant operating costs of other classes of laser-emitting devices.

A major consideration when designing laser-emitting devices is the amount of power that the source laser in the device is required to emit so as to provide adequate laser

emission power from the laser device. One of the determinants of this characteristic is the required power density to be delivered at the application site over a desired area.

As the area required to be treated increases for a required power density so does the power of the source laser needed to support that requirement.

Apart from the power, pulse parameters and wavelength of the laser, another of the critical features in specifying the class of the laser is the apparent aperture of the laser source. The apparent aperture will determine the image size that the laser source can form for example on the retina of an inadvertent observer.

The requirement described above is sometimes referred to as the apparent source and it is this characteristic that is used to determine the class of the laser-emitting device.

Current laser device configurations are restricted somewhat by the physics of the devices used to generate the source laser. For diode laser sources, the emitting aperture (the area of the spot beam) of the laser radiation is typically 7×1 microns for a 904 nanometer Gallium Arsenide (Ga-As) laser diode. These devices typically have pulsed outputs with 1 and 5 Watt peak powers with the pulse repetition and duration being variable to suit the application. There are many other laser diode configurations, the device type described above is an example of such devices.

In some applications it is desired to not only provide the laser radiation over a larger area but also to control the power density thus requiring an adequately high power laser source.

It is an aim of the invention described herein to provide a laser emitting device that meets not only a desired power density and spot area requirement, but that meets Class I requirements thus providing long term minimization of the running costs of the device.

SUMMARY OF THE INVENTION

Accordingly the present invention provides a device for a medical diagnostic or therapeutic purpose, said device including:

laser generating means for generating a laser beam, said laser generating means having an apparent source size;

homogenising means for modifying said laser beam;

wherein said modifying adjusts the apparent source size of said laser beam.

Preferably the homogenising means further modifies a spot size of said laser beam.

Preferably the apparent source size of said laser beam is greater than that required as a minimum condition for classification of said device as a Class I laser.

Preferably the homogenizing means includes an optical homogeniser.

Preferably the optical homogeniser includes a microlens array.

Optionally the optical homogeniser includes a holographic diffuser.

Preferably the device further includes positioning means for positioning said device at a predetermined distance and orientation from a surface according to a requirement of said medical purpose.

BRIEF DESCRIPTION OF THE FIGURES

Specific embodiments of the invention will now be described in some further detail with reference to and as illustrated in the accompanying figures. These embodiments are illustrative, and not meant to be restrictive of the scope of the invention. Suggestions and descriptions of other embodiments may be included within the scope of the invention but they may not be illustrated in the accompanying figures or alternatively

features of the invention may be shown in the figures but not described in the specification.

Fig 1 depicts use of a preferred embodiment of the invention for the treatment of lymphodeama; and

Fig 2 depicts a generic arrangement of a preferred laser-emitting device according to the invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Although a particular medical application is described herein and a particular laser emitting device configuration is also described, it should be understood that these details are illustrative only and not meant to be limiting in any way upon the application or configuration of the principle of the invention.

In the medical field, low power level laser radiation is known to have beneficial medical effects in some disease and restorative therapies.

One example is the treatment of lymphoedema other examples include use of low level laser therapy to induce a photochemical reaction (non-heating) which is used in the treatment of conditions like tendonitis and other soft tissue injuries, wound healing and pain relief.

Clearly, the frequency, power level (continuously on or modulated on/off duty cycle of the radiation at the same or changing levels) and characteristics of the laser are determined by the nature of the treatment outcome desired by a clinician.

The area of effective laser irradiation on the relevant tissue or organ of the patient is a matter of design and specification by the clinician.

Laser source emitting 600-1000 nanometers wavelength at 1mW to 1W power can be used. Such devices are usually class IIIB but by using the invention described herein will become Class 1.

In a preferred arrangement the laser source is a Gallium Arsenide Laser diode having an emitting aperture of 7×1 microns of 904 nanometer wavelength having 5-Watts peak power. In a lymphoedema application such as depicted in Fig 2, the laser output is modulated or controlled to have a low 2,500 Hz and high 5,000 Hz repetition rate of 200-nanosecond duration. Such a device falls near the Class I and adjacent Class IIIB boundary.

As shown in Fig 1, in this type of medical procedure the operator holds the treatment device 20 incorporating the laser emitting device 10 so that the apparent aperture is moved in a predetermined path over the patient's treatment area. The treatment area is usually the tissue in near vicinity of the potentially or actually diseased lymph nodes, under the patients arm (as shown) or the groin area are examples of treatment sites. The treatment device 20 may include a plastic or metal frame 18 that has an abutment surface that is positioned on the treatment area to be irradiated whilst the other end is fixed relative to treatment device 20.

There is exists a slight divergence of the laser beam which is factored into the design, the amount of divergence being directly proportional to the distance between the output aperture of the laser diode and the patient's treatment site.

The invention includes the use of an optical homogeniser such as for example a CORNING™ high performance microlens array. A specification of its characteristics includes that it is made from either fused silica, silicon or polymer-on-silica. It has a center to center spacing tolerance of less than 1 micrometer and a total run-out over 50 mm of less than 7 micrometers. It has a maximum array size of 50 mm by 50 mm, a

maximum substrate diameter of 150 mm and minimum substrate thickness of 400 micrometers.

Characteristics of the microlens are as follows. It can be spherical or aspherical and is designed with a polymer surface irregularity less than one quarter of a wavelength at 633 nanometers. For the silicon oxide (SiO_2) variety at least 97% of the lens surface has a surface irregularity of less than one half of a wavelength at 633 nanometers.

The focal length for a microlens can be designed to vary between 1.5 mm and 6.0 mm at wavelengths greater than or equal to 200 micrometers. The focal length tolerance in air for a polymer microlens is plus or minus 10 micrometers within the array and plus or minus 25 micrometers when measured array to array. For a SiO_2 array the focal length tolerance in air is plus or minus 50 micrometers within the array and plus or minus 50 micrometers when measured array to array.

Clear aperture dimension is less than or equal to 1.3 mm and surface roughness is less than 100 Angstroms $A^\circ(\text{Ra})$. The operating temperature is permitted to be between 0 and 70°C.

The surface relief diffuser version of the microlens array is used in preferred arrangements that are designed to spread light in a predetermined gain distribution. Both symmetric and asymmetric surface relief diffusers can be used dependent on the application. This is not the only type of homogeniser that can be used, there are other fabrication techniques such as holographic diffusers. The important aspect is that the homogeniser acts like a near perfect diffuser thus causing the apparent aperture to be the homogeniser not the aperture of the emitting device.

In the subject application the apparent aperture of the source laser device is made uniformly larger to the order of 6 mm².

The preferred distance between the laser source aperture and the optical homogeniser is 5 mm. This accounts for the divergence of the source laser beam and as a result the apparent aperture and power distribution is such that the full device falls well within Class I limits.

Fig. 2 displays the laser source 10 and a homogeniser element 12 located a distance D1 from the laser source. The slightly divergent laser beam 14 from the source is exaggerated for the purpose of illustration only. The resultant laser beam power distribution is pictorially shown at 16 a distance D2 from the homogeniser element.

Having the arrangement described allows for the power output of the source laser to be increased allowing the ideal required power distribution to be homogeneously distributed over a much greater area than would otherwise be the case. This in turn allows the total laser-radiating device to remain within the Class I laser classification. This ultimately reduces cost to the patient.

A larger area can be treated at the same time, thus reducing treatment time and complexity of movement. This further benefits the patient, as the period of potential discomfort is minimized.

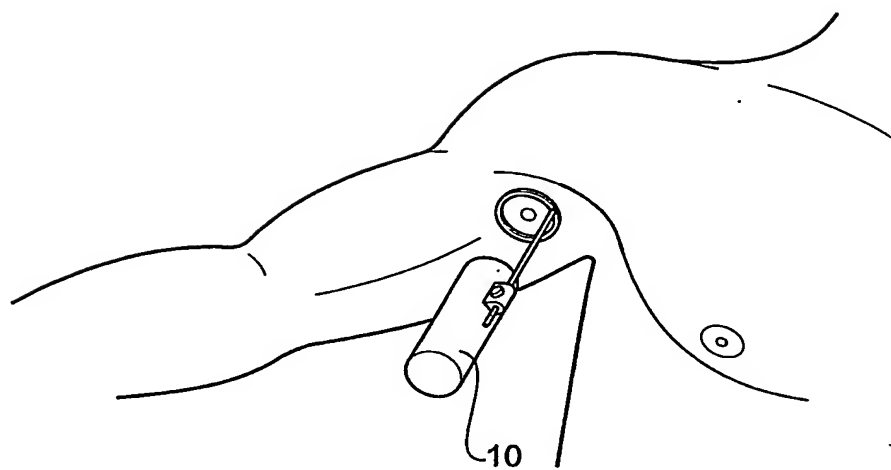
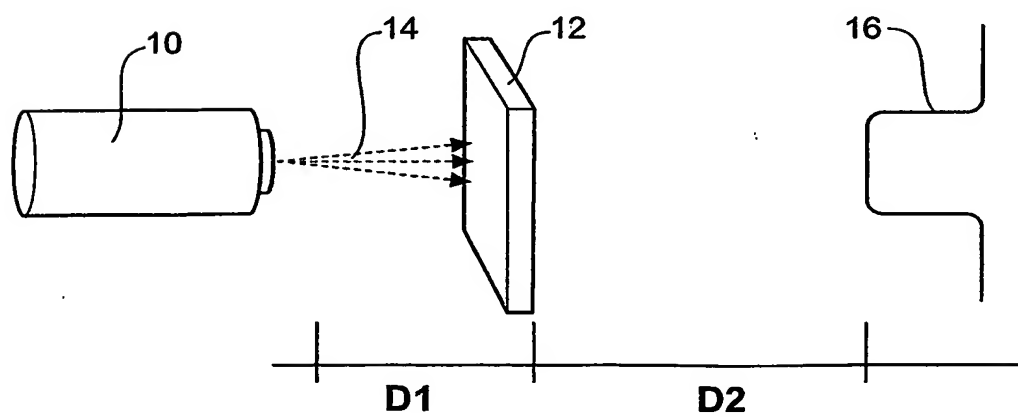
It will be appreciated by those skilled in the art that the invention is not restricted in its use to the particular application described. Neither is the present invention restricted in its preferred embodiment with regard to the particular elements and/or features described or depicted herein. It will be appreciated that various modifications can be made without departing from the principles of the invention. Therefore, the invention should be understood to include all such modifications within its scope.

CLAIMS

1. A device for a medical diagnostic or therapeutic purpose, said device including:
 - laser generating means for generating a laser beam, said laser generating means having an apparent source size;
 - homogenising means for modifying said laser beam;
 - wherein said modifying adjusts the apparent source size of said laser beam.
2. A device as claimed in claim 1, wherein said homogenising means further modifies a spot size of said laser beam.
3. A device as claimed in claim 1 or 2, wherein said apparent source size of said laser beam is greater than that required as a minimum condition for classification of said device as a Class I laser.
4. A device as claimed in any one of claims 1 to 3, wherein said laser generating means includes a laser emitting diode.
5. A device as claimed in any one of claims 1 to 4, wherein said homogenizing means includes an optical homogeniser.
6. A device as claimed in claim 5, wherein said optical homogeniser includes a microlens array.
7. A device as claimed in claim 5, wherein said optical homogeniser includes a holographic diffuser.
8. A device as claimed in any one of the preceding claims wherein said medical diagnostic or therapeutic purpose is the treatment of conditions ameliorated by photochemical low level laser therapy.

9. A device as claimed in any one of the preceding claims wherein said medical diagnostic or therapeutic process is the treatment of lymphoedema.
10. A device as claimed in any one of the preceding claims further including a positioning means for positioning said device at a predetermined distance and orientation from a surface according to a requirement of said medical purpose.
11. A device as claimed in claim 10, wherein said positioning means includes a frame, said frame adjustably attached to said device and when in use for a medical diagnostic or therapeutic purpose providing an abutment surface relative to said treatment area.
12. A device substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings.

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**Fig 1****Fig 2**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/00791

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. 7: A61N 5/067 A61B 6/00 G02B 27/09

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

SEE ELECTRONIC DATABASES CONSULTED

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI JAPIO: laser coheren monochrom light beam wxpand enlag gain spot size sourc distribut intens homogen diffus
holograph microlens medical diagnos therap tissue patient physio restor

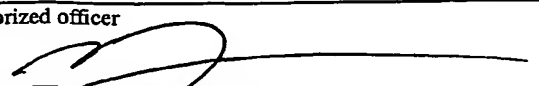
C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/39410 A1 (VISX, INCORPORATED) 5 August 1999 Abstract, Fig. 1, page 7 line 16 - page 10 line 10	1,2,5,7
X	WO 02/056355 (ISHIKAWAJIMA-HARIMA HEAVY INDUSTRIES CO., LTD., SEMICONDUCTOR ENERGY LABORATORY CO., LTD. 15 January 2002 Abstract, Fig.1, whole document	1,2
X	US 5068515 (BERGH) 26 November 1991 Abstract, Fig.	1-5,8,10-11

☒ Further documents are listed in the continuation of Box C

☒ See patent family annex

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

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Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized officer  MATTHEW FORWARD Telephone No : (02) 6283 2606

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/00791

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	SU 1561-062 A (KUIB AVIATION INST) 30 April 1990 Abstract, Fig	1-5
X	WO 95/18984 (COHERENT, INC) 13 July 1995 Abstract, fig.4-8, page 7 line 29 - page 11 line 31.	1,2,5,8

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU03/00791

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	99/39410	AU	25604/99	CA	2319122	EP	1051781
		JP	2002502062				
JP	2002217126						
CA	2033124	DE	59010072	EP	0435825	ES	2081965
		JP	3076879	JP	4251214	RU	2016589
SU	1561062	NO	FAMILY				
WO	9518984	NO	FAMILY				
							END OF ANNEX